



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

MEMORANDUM

Date: June 6, 2019

Subject: Efficacy Review for Valhalla,
EPA Reg. No. 4822-594,
DP Barcode: #451265
E-Submission: #36185

From: Sophie Nguyen
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Kristen Willis, Branch Chief
Product Science Branch
Antimicrobials Division (7510P)
Date Signed: June 6, 2019

To: Eric Miederhoff RM31/Joseph Daniels
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: S.C. Johnson & Son, Inc.
1525 Howe Street
Racine, WI 53403

Formulation from the Label:

<u>Active Ingredient</u>	<u>% by wt.</u>
Alkyl dimethyl benzyl ammonium chloride.....	0.096%
Octyl Decyl Dimethyl Ammonium Chloride	0.072%
Diocetyl Dimethyl Ammonium Chloride	0.036%
Didecyl Dimethyl Ammonium Chloride	0.036%
<u>Other Ingredients</u>	99.760%
Total	100.000%

I. BACKGROUND

Product Descriptions (as packaged, as applied): Foaming aerosol spray product

Submission Type: Formulation amendment

Currently Registered Efficacy Claim(s): Disinfectant (bactericide, virucide) and deodorizer for use on hard, non-porous surfaces.

Requested Action(s): The proposed changes include adding six additional fragrances. To support the addition of this alternate formulation, the company is providing confirmatory efficacy data to demonstrate that the alternate formulation is effective as a disinfectant.

Documents considered in this review:

- Letter from the applicant to the Agency (dated February 4, 2019)
- Application for a Pesticide Amendment (Form 8570-1)
- Proposed Alternate Formulation CSF #19 (8570-4)
- Formulator's Exemption Form (8570-27)
- Certificate with Respect to Citation of Data (Form 8570-34)
- Data Matrices (Form 8570-35)
- Nine efficacy studies (MRID #50770401 - 50770409); Statements of No Data Confidentiality Claims, Good Laboratory Practice Statement, and Quality Assurance Unit Summary are included in each study.
- Proposed label ver. SJD 2/4/2019

II. USE DIRECTIONS

TO DISINFECT(†)(^)(*) (AND DEODORIZE) (HARD, NON-POROUS SURFACES):

Pre-Clean visibly soiled areas.

Spray 6-8 inches from hard non-porous surface(s) until thoroughly wet.

Let stand for 5 minutes.

((Then) (wipe.) ((Wipe with a wet cloth or sponge) (,) (then) (rinse (thoroughly) with water).)

(Rinse food contact surfaces with (clean) (or tap) (or potable) water).

I. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use in Hospital or Medical Environments; Confirmatory Efficacy Data Requirements:

Under certain circumstances, an applicant is permitted to rely on previously submitted efficacy data to support an application or amendment for registration of a product and to submit only minimal confirmatory efficacy data on the applicant's own product to demonstrate the ability to produce an effective formulation. This includes a minor formulation change (e.g., a change in an inert ingredient) in a registered product. Confirmatory data must be developed on the applicant's own finished product. For hospital disinfectants, 10 carriers on each of 2 different batches of products (within the CSF) should be tested against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). For all the methods, the product should kill all the test microorganisms on all carriers. Control carrier counts specifications should be met. For a valid test, no contamination of any carrier is allowed.

Supplemental Claims:

An antimicrobial agent identified as a “one-step” disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, and viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same tolerance level.

II. SYNOPSIS OF SUBMITTED EFFICACY STUDY

1.	MRID	50770401 (Dew Drop Citrus)		
Exp. Start Date:	12/21/2018	Study Completion Date:	1/10/2019	
Study Objective	Hard, non-porous surface disinfectant – confirmatory			
Study Title	AOAC Germicidal Spray Method			
Testing Lab, Lab Study ID	Accuratus Lab Services; Project #A26771			
Test organism(s) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/> 4+	<i>Pseudomonas aeruginosa</i> (ATCC 15442) <i>Staphylococcus aureus</i> (ATCC 6538) <i>Salmonella enterica</i> (ATCC 6538)			
Test Method	Protocol #JW01121218.GS.6 (<i>copy provided</i>)			
Application Method	Ready-to-use, aerosol spray at 6-8 in. for 2-3 sprays			
Test Substance Preparation	Name/ID	Gato-BDD-L Reference No. 17453H117-2L GLP 995		
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	995D4: 0.215% Quat 995D5: 0.214% Quat Analyzed on 12/11/2018		
	Preparation	Ready-to-use		
Soil load	5% FBS			
Carrier type, # per lot	10 glass slide carriers			
Test conditions	Contact time	5 min.	Temp. & RH	19°C & 12% RH
Neutralizer	20 mL Lethen Broth + 0.14% Lecithin + 1.0% Tween 80			
Incubation Time and temp.	46h & 36°C			
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)	Tested at LCL			

2.	MRID	50770402 (Dew Drop Citrus)		
Exp. Start Date:	1/11/2019	Study Completion Date:	1/17/2019	
Study Objective	Hard, non-porous surface disinfectant – confirmatory			
Study Title	AOAC Germicidal Spray Method			
Testing Lab, Lab Study ID	Accuratus Lab Services; Project #A26819			
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+	<i>Staphylococcus aureus</i> (ATCC 6538)			
Test Method	Protocol #JW01010819.GS (<i>copy provided</i>)			
Application Method	Ready-to-use, aerosol spray at 6-8 in. for 2-3 sprays			
	Name/ID	Gato-BDD-L Reference No. 17453H117-2L GLP 995		

Test Substance Preparation	Lots <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	995D5: 0.214% Quat Analyzed on 12/11/2018		
	Preparation	Ready-to-use		
Soil load		5% FBS		
Carrier type, # per lot		60 glass slide carriers		
Test conditions		Contact time	5 min.	Temp. & RH 21°C & 16% RH
Neutralizer		20 mL Lethen Broth + 0.14% Lecithin + 1.0% Tween 80		
Incubation Time and temp.		47h & 36°C		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Tested at LCL. Batch was retested due to failure. No testing conditions were changed.		

3.	MRID	50770403 (Watery Linen)		
Exp. Start Date:		12/27/2018	Study Completion Date:	1/4/2019
Study Objective		Hard, non-porous surface disinfectant – confirmatory		
Study Title		AOAC Germicidal Spray Method		
Testing Lab, Lab Study ID		Accuratus Lab Services; Project #A26761		
Test organism(s) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Pseudomonas aeruginosa</i> (ATCC 15442) <i>Staphylococcus aureus</i> (ATCC 6538) <i>Salmonella enterica</i> (ATCC 6538)		
Test Method		Protocol #JW01121218.GS.1 (<i>copy provided</i>)		
Application Method		Ready-to-use, aerosol spray at 6-8 in. for 3 seconds		
Test Substance Preparation	Name/ID	Gato-B-LIN-L Reference No. 17453H117-1L GLP 994		
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	994D4: 0.211% Quat 994D5: 0.213% Quat Analyzed on 12/11/2018		
	Preparation	Ready-to-use		
Soil load		5% FBS		
Carrier type, # per lot		10 glass slide carriers		
Test conditions		Contact time	5 min.	Temp. & RH 20°C & 31% RH
Neutralizer		20 mL Lethen Broth + 0.14% Lecithin + 1.0% Tween 80		
Incubation Time and temp.		50h & 36°C		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Tested at LCL		

4.	MRID	50770404 (Watery Linen)		
Exp. Start Date:		1/8/2019	Study Completion Date:	1/14/2019
Study Objective		Hard, non-porous surface disinfectant – confirmatory		
Study Title		AOAC Germicidal Spray Method		
Testing Lab, Lab Study ID		Accuratus Lab Services; Project #A26795		
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Staphylococcus aureus</i> (ATCC 6538)		

Test Method		Protocol #JW01010219.GS.1 (<i>copy provided</i>)			
Application Method		Ready-to-use, aerosol spray at 6-8 in. for 3 seconds			
Test Substance Preparation	Name/ID	Gato-B-LIN-L Reference No. 17453H117-1L GLP 994			
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	994D4: 0.211% Quat 994D5: 0.213% Quat Analyzed on 12/11/2018			
	Preparation	Ready-to-use			
Soil load		5% FBS			
Carrier type, # per lot		60 glass slide carriers			
Test conditions		Contact time	5 min.	Temp. & RH	20°C & 17% RH
Neutralizer		20 mL Letheen Broth + 0.14% Lecithin + 1.0% Tween 80			
Incubation Time and temp.		47h & 36°C			
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Tested at LCL. Batch was retested due to failure. No testing conditions were changed.			

5.	MRID	50770405 (Berry Bliss)			
Exp. Start Date:		12/27/2018	Study Completion Date:		1/10/2019
Study Objective		Hard, non-porous surface disinfectant – confirmatory			
Study Title		AOAC Germicidal Spray Method			
Testing Lab, Lab Study ID		Accuratus Lab Services; Project #A26760			
Test organism(s) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Pseudomonas aeruginosa</i> (ATCC 15442) <i>Staphylococcus aureus</i> (ATCC 6538) <i>Salmonella enterica</i> (ATCC 6538)			
Test Method		Protocol #JW01121218.GS.2 (<i>copy provided</i>)			
Application Method		Ready-to-use, aerosol spray at 6-8 in. for 3 seconds			
Test Substance Preparation	Name/ID	Gato-BBB-L Reference No. 17453H117-3L GLP 990			
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	990D4: 0.213% Quat 990D5: 0.216% Quat Analyzed on 12/11/2018			
	Preparation	Ready-to-use			
Soil load		5% FBS			
Carrier type, # per lot		10 glass slide carriers			
Test conditions		Contact time	5 min.	Temp. & RH	18°C & 32% RH
Neutralizer		20 mL Lethen Broth + 0.14% Lecithin + 1.0% Tween 80			
Incubation Time and temp.		46h & 36°C			
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Tested at LCL			

6.	MRID	50770406 (Berry Bliss)		
Exp. Start Date:		1/7/2019	Study Completion Date:	1/10/2019
Study Objective		Hard, non-porous surface disinfectant – confirmatory		

Study Title		AOAC Germicidal Spray Method	
Testing Lab, Lab Study ID		Accuratus Lab Services; Project #A26796	
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Staphylococcus aureus</i> (ATCC 6538)	
Test Method		Protocol #JW01010219.GS.2 (<i>copy provided</i>)	
Application Method		Ready-to-use, aerosol spray at 6-8 in. for 3 seconds	
Test Substance Preparation	Name/ID	Gato-BBB-L Reference No. 17453H117-3L GLP 990	
	Lots <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	990D4: 0.213% Quat Analyzed on 12/11/2018	
	Preparation	Ready-to-use	
Soil load		5% FBS	
Carrier type, # per lot		60 glass slide carriers	
Test conditions		Contact time	5 min. Temp. & RH 20°C & 34% RH
Neutralizer		20 mL Lethen Broth + 0.14% Lecithin + 1.0% Tween 80	
Incubation Time and temp.		48h & 36°C	
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Tested at LCL Batch was retested due to failure. No testing conditions were changed.	

7.	MRID	50770407 (Tropical Flowers)		
Exp. Start Date:		12/28/2018	Study Completion Date:	1/4/2019
Study Objective		Hard, non-porous surface disinfectant – confirmatory		
Study Title		AOAC Germicidal Spray Method		
Testing Lab, Lab Study ID		Accuratus Lab Services; Project #A26759		
Test organism(s) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Pseudomonas aeruginosa</i> (ATCC 15442) <i>Staphylococcus aureus</i> (ATCC 6538) <i>Salmonella enterica</i> (ATCC 6538)		
Test Method		Protocol #JW01121218.GS.3 (<i>copy provided</i>)		
Application Method		Ready-to-use, aerosol spray at 6-8 in. for 3 seconds		
Test Substance Preparation	Name/ID	Gato-BTF-L Reference No. 17453H117-4L GLP 991		
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	991D4: 0.212% Quat 991D5: 0.214% Quat Analyzed on 12/11/2018		
	Preparation	Ready-to-use		
Soil load		5% FBS		
Carrier type, # per lot		10 glass slide carriers		
Test conditions		Contact time	5 min.	Temp. & RH 20°C & 19% RH
Neutralizer		20 mL Lethen Broth + 0.14% Lecithin + 1.0% Tween 80		
Incubation Time and temp.		49h & 36°C		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Tested at LCL		

8.	MRID	50770408 (Camellia)		
Exp. Start Date:	12/28/2018	Study Completion Date:	1/4/2019	
Study Objective	Hard, non-porous surface disinfectant – confirmatory			
Study Title	AOAC Germicidal Spray Method			
Testing Lab, Lab Study ID	Accuratus Lab Services; Project #A26758			
Test organism(s) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/> 4+	<i>Pseudomonas aeruginosa</i> (ATCC 15442) <i>Staphylococcus aureus</i> (ATCC 6538) <i>Salmonella enterica</i> (ATCC 6538)			
Test Method	Protocol #JW01121218.GS.4 (copy provided)			
Application Method	Ready-to-use, aerosol spray at 6-8 in. for 3 seconds			
Test Substance Preparation	Name/ID	Gato-BC-L Reference No. 17453H117-5L GLP 992		
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	992D4: 0.214% Quat 992D5: 0.214% Quat Analyzed on 12/11/2018		
	Preparation	Ready-to-use		
Soil load	5% FBS			
Carrier type, # per lot	10 glass slide carriers			
Test conditions	Contact time	5 min.	Temp. & RH	21°C & 15% RH
Neutralizer	20 mL Lethen Broth + 0.14% Lecithin + 1.0% Tween 80			
Incubation Time and temp.	46h & 36°C			
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)	Tested at LCL			

9.	MRID	50770409 (Orchard Fruit)		
Exp. Start Date:	1/2/2019	Study Completion Date:	1/8/2019	
Study Objective	Hard, non-porous surface disinfectant – confirmatory			
Study Title	AOAC Germicidal Spray Method			
Testing Lab, Lab Study ID	Accuratus Lab Services; Project #A26770			
Test organism(s) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/> 4+	<i>Pseudomonas aeruginosa</i> (ATCC 15442) <i>Staphylococcus aureus</i> (ATCC 6538) <i>Salmonella enterica</i> (ATCC 6538)			
Test Method	Protocol #JW01121218.GS.5 (copy provided)			
Application Method	Ready-to-use, aerosol spray at 6-8 in. for 3 seconds			
Test Substance Preparation	Name/ID	Gato-BOF-L Reference No. 17453H117-6L GLP 993		
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	992D4: 0.211% Quat 992D5: 0.211% Quat Analyzed on 12/11/2018		
	Preparation	Ready-to-use		
Soil load	5% FBS			
Carrier type, # per lot	10 glass slide carriers			
Test conditions	Contact time	5 min.	Temp. & RH	19°C & 12% RH
Neutralizer	20 mL Lethen Broth + 0.14% Lecithin + 1.0% Tween 80			
Incubation Time and temp.	46h & 36°C			

Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)	Tested at LCL
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III. RESULTS

Bactericidal Activity – Confirmatory Data – Dew Drop Citrus					
Contact Time	MRID Number	Organism	No. Carriers Exhibiting Growth/Total Carriers		Carrier Population (Average Log ₁₀ CFU/Carrier)
			Batch 995D4	Batch 995D5	
RTU aerosol spray					
5 min.	50770401	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	0/10	0/10	5.69
		<i>Salmonella enterica</i> (ATCC 10708)	0/10	0/10	4.57
		<i>Staphylococcus aureus</i> (ATCC 6538)	0/10	1/10	5.48
	50770402	<i>Staphylococcus aureus</i> (ATCC 6538)	--	1/60	5.47

Bactericidal Activity – Confirmatory Data – Watery Linen					
Contact Time	MRID Number	Organism	No. Carriers Exhibiting Growth/Total Carriers		Carrier Population (Average Log ₁₀ CFU/Carrier)
			Batch 994D4	Batch 994D5	
RTU aerosol spray					
5 min.	50770403	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	0/10	0/10	5.02
		<i>Salmonella enterica</i> (ATCC 10708)	0/10	0/10	4.70
		<i>Staphylococcus aureus</i> (ATCC 6538)	2/10	1/10	5.57
	50770404	<i>Staphylococcus aureus</i> (ATCC 6538)	0/60	0/60	5.59

Bactericidal Activity – Confirmatory Data – Berry Bliss					
Contact Time	MRID Number	Organism	No. Carriers Exhibiting Growth/Total Carriers		Carrier Population (Average Log ₁₀ CFU/Carrier)
			Batch 990D4	Batch 990D5	
RTU aerosol spray					

5 min.	50770405	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	0/10	0/10	5.02
		<i>Salmonella enterica</i> (ATCC 10708)	0/10	0/10	4.64
		<i>Staphylococcus aureus</i> (ATCC 6538)	1/10	0/10	5.38
	50770406	<i>Staphylococcus aureus</i> (ATCC 6538)	1/60	--	5.38

Bactericidal Activity – Confirmatory Data – Tropical Flowers					
Contact Time	MRID Number	Organism	No. Carriers Exhibiting Growth/Total Carriers		Carrier Population (Average Log ₁₀ CFU/Carrier)
			Batch 991D4	Batch 991D5	
RTU aerosol spray					
5 min.	50770407	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	0/10	0/10	5.05
		<i>Salmonella enterica</i> (ATCC 10708)	0/10	0/10	4.25
		<i>Staphylococcus aureus</i> (ATCC 6538)	0/10	0/10	5.46

Bactericidal Activity – Confirmatory Data – Camellia					
Contact Time	MRID Number	Organism	No. Carriers Exhibiting Growth/Total Carriers		Carrier Population (Average Log ₁₀ CFU/Carrier)
			Batch 992D4	Batch 992D5	
RTU aerosol spray					
5 min.	50770408	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	0/10	0/10	5.04
		<i>Salmonella enterica</i> (ATCC 10708)	0/10	0/10	4.52
		<i>Staphylococcus aureus</i> (ATCC 6538)	0/10	0/10	5.42

Bactericidal Activity – Confirmatory Data – Orchard Fruit					
Contact Time	MRID Number	Organism	No. Carriers Exhibiting Growth/Total Carriers		Carrier Population (Average Log ₁₀ CFU/Carrier)
			Batch 993D4	Batch 993D5	
RTU aerosol spray					

5 min.	50770409	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	0/10	0/10	5.87
		<i>Salmonella enterica</i> (ATCC 10708)	0/10	0/10	4.67
		<i>Staphylococcus aureus</i> (ATCC 6538)	0/10	0/10	5.49

IV. CONCLUSION

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50770401	Bactericidal activity (Dew Drop Citrus)	Hard, non-porous surfaces	RTU aerosol spray	5 min.	5% FBS	--	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	Yes
							<i>Salmonella enterica</i> (ATCC 10708)	Yes
							<i>Staphylococcus aureus</i> (ATCC 6538)	No
50770402 (batch repeat)	Bactericidal activity (Dew Drop Citrus)	Hard, non-porous surfaces	RTU aerosol spray	5 min.	5% FBS	--	<i>Staphylococcus aureus</i> (ATCC 6538)	No*
50770403	Bactericidal activity (Watery Linen)	Hard, non-porous surfaces	RTU aerosol spray	5 min.	5% FBS	--	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	Yes
							<i>Salmonella enterica</i> (ATCC 10708)	Yes
							<i>Staphylococcus aureus</i> (ATCC 6538)	No
50770404 (batch repeat)	Bactericidal activity (Watery Linen)	Hard, non-porous surfaces	RTU aerosol spray	5 min.	5% FBS	--	<i>Staphylococcus aureus</i> (ATCC 6538)	No*
50770405	Bactericidal activity (Berry Bliss)	Hard, non-porous surfaces	RTU aerosol spray	5 min.	5% FBS	--	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	Yes
							<i>Salmonella enterica</i> (ATCC 10708)	Yes
							<i>Staphylococcus aureus</i> (ATCC 6538)	No
50770406 (batch repeat)	Bactericidal activity (Berry Bliss)	Hard, non-porous surfaces	RTU aerosol spray	5 min.	5% FBS	--	<i>Staphylococcus aureus</i> (ATCC 6538)	No*
50770407	Bactericidal activity	Hard, non-	RTU aerosol spray	5 min.	5% FBS	--	<i>Pseudomonas aeruginosa</i>	Yes

	(Tropical Flowers)	porous surfaces					(ATCC 15442)	
							<i>Salmonella enterica</i> (ATCC 10708)	Yes
							<i>Staphylococcus aureus</i> (ATCC 6538)	Yes
50770408	Bactericidal activity (Camellia)	Hard, non-porous surfaces	RTU aerosol spray	5 min.	5% FBS	--	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	Yes
							<i>Salmonella enterica</i> (ATCC 10708)	Yes
							<i>Staphylococcus aureus</i> (ATCC 6538)	Yes
50770409	Bactericidal activity (Orchard Fruit)	Hard, non-porous surfaces	RTU aerosol spray	5 min.	5% FBS	--	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	Yes
							<i>Salmonella enterica</i> (ATCC 10708)	Yes
							<i>Staphylococcus aureus</i> (ATCC 6538)	Yes

***Note: Repeat testing for 10 carriers tests where the product did not meet the performance criteria are not acceptable. A parameter of the test such as contact time or soil load should be a changed in order to continue testing.**

V. LABEL RECOMMENDATIONS (for label dated 2/4/2019)

1. The following proposed label claims are acceptable regarding the use of the product, Valhalla (EPA Reg. No. 4822-594), as a ready to use aerosol spray disinfectant with the following fragrances against the following organisms on hard, nonporous surfaces for a 5-minute contact time:

Fragrance- Tropical Flowers:

Pseudomonas aeruginosa (ATCC 15442)

Staphylococcus aureus (ATCC 6538)

Salmonella enterica (ATCC 10708)

Fragrance- Camellia:

Pseudomonas aeruginosa (ATCC 15442)

Staphylococcus aureus (ATCC 6538)

Salmonella enterica (ATCC 10708)

Fragrance- Orchard Fruit:

Pseudomonas aeruginosa (ATCC 15442)

Staphylococcus aureus (ATCC 6538)

Salmonella enterica (ATCC 10708)

These claims are supported by the submitted data.

2. The following proposed label claims are **not acceptable** regarding the use of the product, Valhalla (EPA Reg. No. 4822-594), as a ready to use aerosol spray disinfectant with the following fragrances against the following organisms on hard, nonporous surfaces for a 5-minute contact time:

Fragrance- Dew Drop Citrus:

Pseudomonas aeruginosa (ATCC 15442)

Staphylococcus aureus (ATCC 6538)

Salmonella enterica (ATCC 10708)

Fragrance- Watery Linen:

Pseudomonas aeruginosa (ATCC 15442)

Staphylococcus aureus (ATCC 6538)

Salmonella enterica (ATCC 10708)

Fragrance- Berry Bliss:

Pseudomonas aeruginosa (ATCC 15442)

Staphylococcus aureus (ATCC 6538)

Salmonella enterica (ATCC 10708)

The product does not meet the performance criteria as a disinfectant due to the failing *Staphylococcus aureus* data. Remove these fragrances from the label.

3. All claims against cold viruses should be removed from the label. Product did not demonstrate effectiveness against at least two of the required organisms (Rhinovirus, Coronavirus, and Respiratory Syncytial Virus) to qualify for the claims. Our records showed that the study with MRID #49407501 belonging to the product with Reg. No. 4822-607 was never submitted or cited for review for Valhalla (Reg. No. 4922-594). If the registrant has a copy of the efficacy review for Valhalla that approved the study for Human Coronavirus, please provide it to the agency at this time for verification.
4. Throughout the label, remove the word “wipe” when used ambiguously or when used with public health claims (e.g., germs). This word is misleading because the product is tested as a spray and not a towelette. The following claims should be revised:
 - a. “(Brand name) Wipes out tough grime and (household) germs†!”
 - b. “Wipes out tough grime and (household) germs†!”
 - c. “All you have to do is wipe (!)”
 - d. “One wipe and (you are) (you’re) done(!)”
 - e. “Simply dab, wipe and (flush) (throw) away”
5. Throughout the label, revise “when use-directions are followed” to “when use-directions for disinfection are followed”. Additionally, remove brackets from this phrase or place an asterisk after “One-Step”.

6. Throughout the label, when the word “quick” or “fast” is being used, it should describe cleaning. This also means removing brackets from mandatory wording. For example, these claims should be revised to:
 - a. Page 11 – “Fast acting foam (penetrates hard to reach places for easy)~~(cleaning)~~.”
 - b. Page 14 – “The (fastest) (easiest) (most convenient) way to~~(clean-up)~~(everyday) (little) (messes).”
 - c. Page 10 – “(Easy) (Quick cleaner) (&) (Convenient) (to use) (in) (insert location - Table 3) (&) (throughout the house)” and “(Easy) (Quick cleaner) (and) (Convenient) (to use) (in) (the) (bathroom) (and) (Kitchen) (throughout the house)
 - d. Page 12 – “Makes (bathroom) (kitchen) (Office)(Family Room)(Den)(Car)~~(clean-ups)~~(touch-up(s)) quick and easy”.
7. On page 7,
 - a. Qualify “viruses” in the claim “(Kills) (bacteria*) (disinfectant effective against (This Product kills) (many types of) (household) bacteria (and viruses), including (insert organisms – Section 5)”, “Kills the viruses that cause (the common) cold(s) and flu”,
 - b. Revise the claim “(Kills) (Eliminates) (Destroys) 99.9% (of bacteria*) (of the bacteria* commonly found in) (all around) (your) (insert locations – Table 3) (including) (insert organism – Section 5)” to “(Kills) (Eliminates) (Destroys) 99.9% (of bacteria*) (of the bacteria* commonly found ~~in~~) on hard, nonporous surfaces in (~~all around~~)(~~your~~) (insert locations – Table 3) (including) (insert organism – Section 5).
 - c. Remove “Eliminates” from the claim “(Kills) (Eliminates) (Destroys) bacteria* from (insert location – Table 3) surfaces.” This term implies complete kills. The claim to “eliminate 99.9% bacteria” is acceptable.
8. On page 8,
 - a. Remove “in 30 seconds” from the claim “Disinfects (household) (bathroom) (surfaces) (insert location – Table 3) in 30 seconds”. This is false and misleading since efficacy data did not demonstrate killing of microorganisms in 30 seconds.
 - b. Remove “Eliminates” from the claim “(Stops) (Kills) (Eliminates) (germs‡) (microbes‡) (microorganisms‡) (bacteria*) (viruses^)^ where (they) (it) (live(s) (hide(s) (hide(s) out) (reside(s) (lurk(s) (lie(s) in wait) (where germs‡ are a concern)”.
9. On page 11, the claim “(Foam) Goes to work on contact (penetrating) (and) (dissolving) (grime)” should be revised to remove brackets from “dissolving grime” so that the claim is not being confused as a public health claim.
10. On page 13,
 - a. The claim “Penetrating foam works on contact” should be qualified by adding a non-public health use to this claim (e.g., cleaner). For example, “Penetrating foam cleans on contact”.
 - b. Remove brackets from “cleaner” in the claim “Powerful (cleaner) (aerosol) (spray)”.

11. On page 15, “hard, non-porous surfaces” (without brackets) should be added to the claim “Use in the kitchen, bathroom and (throughout) (all around) (the whole house) (your home) (your house)” and “Use (throughout) (everywhere in) (all around) (the) (your) (whole) (home) (house) (locations from Table 3) (!)”.